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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/337,675	06/22/1999	JON SWANSON	029318/0497	9275

31049 7590 08/30/2010

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
08/30/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/337,675	SWANSON ET AL.	
	Examiner	Art Unit	
	S. TRAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-22,25-36,38-40,42-44,46-48 and 50-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-22,25-36,38-40,42-44,46-48 and 50-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *all*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The rejections of record have been withdrawn in view of Applicant's Remarks and Amendment filed 07/19/10.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/19/10 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 8-13, 30-36, 38-40, 46-48 and 50-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Levy et al. WO 96/20698 A2.

Levy teaches a biodegradable controlled release nanoparticles comprising a nanoparticulate drug composition and at least one high molecular weight polymer (abstract, pages 7-8; and claims). The nanoparitcles have average diameter less than

300 nm (page 6, lines 13-18). Levy also teaches that the polymer is incorporated in the nanoparticles as a polymer matrix (page 7, lines 1-7; and page 22, lines 18 through page 23, lines 1-5). Drugs are disclosed in pages 11-12. Drug composition also comprises a surface modifying agent that adsorbing or adhering on the nanoparticles (pages 12-15; and page 20, lines 11-20). The nanoparticles are incorporated in an oral dosage form that releases the drug in periods of time ranging from 4-9 hours (page 107, lines 5-11; and page 110). The oral dosage form such as capsule is coated with enteric polymers such as cellulose acetate phthalate, shellac, and Eudragit polymers for controlling the release time of the drug (page 106, lines 5 through page 107, lines 1-11).

Claim Rejections - 35 USC § 103

Claims 1, 2, 4-22, 25-36, 38-40, 42-44, 46-48 and 50-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al., in view of Liversidge et al. WO 99/02665 A1.

Levy is relied upon for the reasons stated above. Levy does not teach tablet comprising nanoparticles, and pharmaceutically acceptable excipients.

Liversidge teaches a solid dosage form comprising: 1) nanoparticulate drug having effective average particle size less than about 1000 nm, preferably less than 400 nm; and 2) binder, filler, lubricant, disintegrant, and other excipients (page 5, paragraphs 2-6; and page 7, paragraphs 2-3). Liversidge further teaches a process for preparing the solid dosage form (page 16, last paragraph through page 19).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the nanopartilces of Levy, to include the use of pharmaceutical excipients. This is because Liversidge teaches that it is well known to include excipients such as binder, filler, lubricant, disintegrant and other excipients in an oral dosage form, and because Levy teach the desirability for incorporating the nanoparticles into an oral dosage form.

Response to Arguments

Applicant's arguments filed 07/19/10 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. TRAN whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. TRAN/
Primary Examiner, Art Unit 1615